REMARKS

In view of the foregoing amendments and following remarks responsive to the Office Action of February 9, 2005, Applicant respectfully requests favorable reconsideration of this application.

Claims 1-26 were pending in this application. Claims 19-26 we previously withdrawn. Applicant has herein amended claims 10, 11, 14, and 15, added new claims 27-29, and canceled claims 12 and 19-26. Accordingly, claims 1-11, 13-16, and 27-29 are now pending in this application.

Applicant respectfully thanks the Office for the indication that claims 14-16 are merely objected to as depending upon a rejected base claim, but would be allowable if rewritten into independent form. Applicant has amended claims 14-16 into independent form. Accordingly, they should now be allowable claims.

The Office rejected claims 1-13 and 17 under 35 U.S.C. §102(b) as being anticipated by Lau. The Office redundantly rejected claims 1-9, 13, 17, 18 under 35 U.S.C. §102(b) as being anticipated by DiCaprio.

The Present Invention

The present invention pertains to a stent delivery system particularly adapted to assure that the stent is not inadvertently moved by the delivery apparatus in the body lumen during the implantation process. Particularly, the stent delivery mechanism comprises a catheter having an outer tube and an inner tube designed to hold the stent within the outer tube in a radially constricted condition. More specifically, the stent is positioned between the outer surface of

the inner tube and the inner surface of the outer tube. One or more inflatable balloons are carried on the inner tube at or near the location of the loaded stent. The balloon or balloons may be axially aligned with the stent, i.e., the stent is mounted over the balloons on the inner tube.

For implantation, the assembly is inserted into the body lumen with the outer tube essentially protecting the stent. The outer tube and inner tube are not moved relative to each other during this positioning. The balloon is inflated to an internal pressure or volume that is small enough so that the frictional force between the balloon and the inner surface of the outer tube is not so great that it is impossible or difficult to slide the outer tube relative to the inner tube, but is high enough to keep the stent from moving with respect to the inner tube when the outer tube is slid relative to the inner tube and balloon. The outer tube is then withdrawn, thereby exposing the stent to the vessel. The balloon preferably is formed of a material that is more compliant than the outer tube so that the stent will take a greater set against the balloon than it will against the outer tube, thus holding the balloon in place longitudinally relative to the inner tube when the outer tube is moved longitudinally.

The Lau Reference

Lau discloses a stent delivery apparatus in which an expandable stent 10 is mounted over a balloon 14 mounted on a catheter 11. The catheter, balloon, and stent optionally may be disposed inside of a retractable protective delivery sleeve 20. Column 4, lines 31-62. The purpose of the retractable protective

delivery sleeve 20 is described as "to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevent abrasion of the body lumen by the open surface of the stent 20 [sic, 14] during delivery to the desired arterial location." Column 4, lines 44-48.

There is no mention in Lau of the stent being trapped between the outer surface of the balloon and the inner surface of the delivery sleeve 20. Rather, "the stent 10 is compressed onto the balloon" (column 4, lines 39-40). Furthermore, "the balloon 14 is slightly inflated to secure the stent 10 onto the exterior of the balloon" (column 4, lines 60-62).

Lau's design is essentially conventional and is directed toward balloon expandable stents, not self expanding stents. As such, the purpose of the balloon in Lau is to expand the stent when it is released from the delivery mechanism. When the catheter has been advanced so that the stent (and balloon) is at the deployment site, the balloon is then fully expanded to cause the stent to expand to meet the walls of the body lumen. The balloon is then deflated and the catheter and guide wire are then removed, leaving the stent in place.

The DiCaprio Reference

For purposes relevant to the claims of the instant application, DiCaprio is essentially identical to Lau. Particularly, it discloses a stent 14 mounted over a balloon 22 mounted on a shaft 13 and an optional retractable delivery shaft 11

(typically called a guide catheter, shown retracted in Figure 2). Column 6, lines 19-25.

As was the case with respect to Lau, the purpose of the balloon is to be expanded after the delivery shaft, if one is even used, is retracted so as to expand the stent against the wall of the body lumen. The balloon does not trap the stent between the balloon and the delivery shaft 11. This is quite clearly shown in Figure 1, the only figure of DiCaprio that shows the stent within the delivery shaft 11. Particularly, quite clearly there is a gap between the delivery shaft 11 and the stent 14.

Traversal

With respect to the rejection based on Lau, Applicant respectfully traverses as Lau does not teach the basic premise of the present invention, namely, inflating the balloon prior to releasing the stent from the outer tube so as to trap the stent between the outer surface of the balloon and the inner surface of the outer tube.

Perhaps this is made most clear in Lau by the fact that the delivery sleeve 20 is optional, its purpose being to further ensure that the stent stays in place on the expandable portion of he delivery catheter 11 because it prevents abrasion of the body lumen by the stent (col. 4, lines 41-48). The problem with delivering a self-expanding stent, which is the subject of the present invention, is that, with a self expanding stent, one has the exact opposite problem than that described in the above quote from Lau. That is, the problem addressed by the present

invention is that is that the outer tube tends to draw a self-expanding stent with it when retracted because the stent is forcing itself against the inner surface of the outer tube. This is exactly opposite to Lau's statement that the optional delivery sleeve "further ensure(s) that the stent stays in place."

Lau is primarily concerned with balloon expandable stents. That is why the Lau delivery apparatus includes a balloon. In fact, Lau expressly states that delivery catheter 11 "is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures" (col. 4, lines 30-33). With balloon expandable stents such as are the subject of Lau, drawing stent along with the delivery sleeve is not an issue because the stent is not in contact with the sleeve. Rather, it is "compressed onto the balloon" (col. 4, lines 40-41).

The present invention is fundamentally different from Lau because it is concerned with self expanding stents that are not compressed onto the balloon because a self expanding stent inherently applies force in the opposite direction, i.e., an expansion force. Unlike the stents discussed in Lau, the self expanding braided stents that are the primary focus of the present invention force themselves against the inner surface of the outer tube. In the present invention, this makes it difficult to retract the outer tube without also retracting the stent.

Note that Lau states that the balloon is caused to stay on the balloon by being "compressed on the balloon" or by "other means . . ." such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon" (col. 4, lines 37-50). This is consistent with Lau's focus on delivering balloon expandable stents. A self-expanding stent cannot be secured to a

balloon (1) by being compressed onto the balloon by, (b) by collars or ridges at the ends of the balloon, and/or by slightly inflating the balloon. A self expanding stent would simply radially expand until it either reached its nominal diameter or hit something that prevented it from further expansion (such as hitting the outer tube).

Perhaps the Office is confused by the fact that Lau states that "[t]he balloon is slightly inflated to secure the stent 10 onto the exterior of the balloon" (col. 4, lines 60-62), while the present specification states that the balloon is partially expanded so as to trap the stent between the balloon and the outer tube. These two statements may seem similar when taken out of context. However, in context, it is clear that Lau is not contemplating inflating the balloon so as to trap the stent between the balloon and the outer tube, but is merely contemplating slightly inflating the balloon so that the balloon contacts the non self expanding stent without expanding it. Specifically, even a compressed non self expanding stent obviously will not be secured to the balloon unless the balloon is inflated to the diameter of the stent. Thus, merely stating that the balloon is slightly inflated to secure the stent to the balloon (particularly, when taken in the context of Lau's non self expanding stents) is a far cry from disclosing expanding the balloon so as to trap the stent between an outer tube and the balloon.

While Lau does mention the possibility of using superelastic stents, the purpose of the balloon in Lau is still to expand the stent upon release from the delivery apparatus and not to trap the stent between balloon and the outer tube.

Even a superelastic stent has little or no expansion force until it is released from the delivery apparatus.

Quite simply, Lau discloses conventional technology for delivery of balloon expandable stents, in which the stent is mounted on a balloon inside of an outer tube, but is not trapped against the outer tube. See, for instance, the DiCaprio reference that also was cited by the Office (and which is discussed further below) in which the stent is mounted on a balloon with the stent and balloon within a delivery sheath, but the stent does not contact the delivery sheath.

Hence, Lau does not disclose the limitation of claim 1 of "inflating said balloon so as to trap said stent between said balloon and said outer tube".

The dependent claims add even further distinguishing features. For instance, claims 10 and 11 both add that the stent is a self expanding braided stent. Lau discloses only balloon expandable stents and superelastic stents. Also as noted above, this difference is crucial since self expanding braided stents apply a strong radial expansion force while inside the delivery apparatus, thus making it difficult to retract the outer tube while not carrying the stent along with it. Superelastic stents and balloon expandable stents do not have this problem.

Dependent claim 27 even further distinguishes over Lau as it adds that the balloon has a nominal diameter that is smaller than the diameter of the body lumen. The reason that this is a desirable feature in the present invention is because the balloon needs to trap the stent between the balloon and the outer tube in such a way that the stent will stay with the balloon and not move with the outer tube, while also assuring that the force of the balloon against the outer tube

is not so great as to make it difficult or impossible to withdraw the outer tube. Accordingly, the balloon nominal diameter should, not only be smaller than the body lumen, but smaller than the outer tube (as discussed on page 11, line 14-page 12, line 4 of the present application).

This is clearly contrary to the teachings of Lau in which the balloon must expand to the size of the body lumen since the purpose of the balloon is to expand the stent to at least the size of the body lumen.

Claim 28 also further distinguishes over Lau in the same manner as claim 27. Specifically, claim 28 adds that the nominal diameter of the balloon is "less than said inner diameter of said outer tube but greater than said inner diameter of said outer tube minus said thickness of said stent".

Finally, claim 29 even further distinguishes over Lau in that it recites that the "balloon is formed of a material that is more compliant than a material from which said outer tube is formed". This is an important feature as it is important that the stent take a set against the balloon rather than the outer tube so that the stent will stay with the balloon rather than the outer tube when the outer tube is retracted relative to the balloon and inner tube. As should be expected, this feature is nowhere mentioned in Lau, since Lau simply is not concerned with the same issues as the present invention.

Turning to the DiCaprio reference, it is essentially identical to Lau in all respects relevant to the patentability of the present claims. In fact, the distinctions are much clearer in DiCaprio because of better drawings in DiCaprio. Specifically, as noted above, DiCaprio, like Lau, does not trap the stent between

the balloon and the delivery sheath as claimed in claim 1. This is quite apparent in Figure 1, in which a gap between the stent and the outer sheath is quite visible. DiCaprio also does not teach the other distinguishing feature discussed above of the balloon being of a nominal diameter less than the diameter of the body lumen on the outer sheath (claims 27 and 28, respectively). Specifically, the purpose of the balloon is to expand the stent to at least the diameter of the body lumen and therefore, it must have a nominal diameter sufficient to do so. Also, there is no mention of the balloon being more compliant than the outer tube (claims 29).

Thus, the claims distinguish over DiCaprio for at least all of the same reasons discussed above in connection with Lau.

In view of the foregoing amendments and remarks, this application is now in condition for allowance. Applicant respectfully requests the Examiner to issue a Notice of Allowance at the earliest possible date. The Examiner is invited to contact Applicant's undersigned counsel by telephone call in order to further the prosecution of this case in any way.

Respectfully submitted,

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